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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,598	12/12/2003	Scott Freeberg	279.441US1	1744
21186	7590	02/23/2006		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			EXAMINER KRAMER, NICOLE R	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/735,598	FREEBERG; SCOTT	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/28/05</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-20 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,161,042 ("Hartley et al.") in view of WO 00/78391 ("Salo et al"), which corresponds to U.S. Patent No. 6,278,894. For convenience purposes, Examiner's citations to Salo et al. refer to citations in the corresponding U.S. Patent document.

Hartley et al. discloses a cardiac rhythm management device that detects transthoracic impedance, extracts minute ventilation information therefrom, and adjusts a delivery rate of the pacing therapy according to the extracted minute ventilation information. More specifically, the device includes an exciter coupled to a thorax of a patient for repeatedly delivering a multiphase stimulus thereto, a signal processor for obtaining transthoracic impedance information responsive to the stimuli, a demodulator that includes sampling elements for demodulating the impedance in response to different phases of the stimulus, a controller for adjusting the rate of delivery of pacing therapy based on the transthoracic impedance information, and a therapy circuit for delivering therapy to the heart of a patient (see col. 3, line 60 - col. 4, line 6). A minute ventilation signal is derived from the impedance signal for indicating a metabolic need

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for an increased heart rate (see col., 6, lines 30-50). The device ignores the MV information when a noise-measurement exceeds a threshold (see Abstract). More specifically, the demodulator 415 provides the noise sensing mode or operation for detecting noise when no excitation current is supplied and for computing an average noise level. If the detected noise is above a threshold value, subsequent circuits ignore the output of the demodulator until the detected noise falls below the threshold value (see col. 12, lines 11--48).

Hartley et al. fails to disclose a switch matrix with the capability of switching between different electrode configurations for use as voltage sense electrodes, and circuitry for operating the switch matrix to select a configuration of voltage sense electrodes for use by the device that result in the lowest average noise level. Salo et al. teaches a cardiac rhythm management device which teaches a switch matrix (42; see col. 4, lines 15-33) for switching between different electrode configurations for use as voltage sense electrodes in order to select combinations of electrodes with improved signal-to-noise ratios, thereby significantly improving the quality of the impedance measurement (see, for example, col. 3, lines 3-5 and col. 6, lines 5-11). In addition to or rather than ignoring the MV information when the detected noise exceeds a threshold value, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the device of Hartley et al. to include a switch matrix for switching between different electrode configurations for use as voltage sense electrodes as taught by Salo et al. in order to select combinations of electrodes with improved signal-to-noise ratios, thereby significantly improving the quality of the impedance

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measurement. Selection of an electrode combination having an improved signal-to-noise ratio would significantly improve the quality and reliability of the MV information, and thus allow the cardiac rhythm management device of Hartley et al. to continuously deliver appropriate CRM therapy.

With respect to claims 2, 3, 14, and 15, selection of a configuration of voltage sense electrodes for use by the device that results in the highest signal-to-noise ratio would be obvious to one having ordinary skill in the art in order to enhance the quality and reliability of the MV information as much as possible.

Further with respect to claims 3, 7, 15, and 19, Salo et al. teaches that the switch matrix has the capability of selecting one or several electrodes to function either as a drive electrode or a sense electrode (see col. 4, lines 15-20).

With respect to claims 4-5 and 16-17, Hartley et al. discloses that various electrode configurations, including that header 140 may include an indifferent electrode (see col. 5, line 57 - col. 6, line 30).

With respect to claims 6 and 18, Salo et al. teaches that the plurality of selectable voltage sense and excitation current electrodes include the tip and ring electrodes of a plurality of sensing/pacing leads (leads 12, 14, and 15).

With respect to claims 8, 10, and 20, Hartley et al. discloses that the circuitry for demodulating the voltage sense signal samples generates a weighted average of the voltage sense signal samples (see col. 11, lines 1-33).

With respect to claim 9, Hartley et al. discloses that the excitation current waveform is output as a strobe made up of a specified number of excitation current

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waveform cycles with each strobe repeated at a specified strobing frequency (exciter 150 delivers an electrical excitation signal, such as a strobed sequence of current pulses; see col. 6, lines 17-30).

With respect to claim 11, Hartley discloses that the voltage sense signal signals are further filtered into the ventilation band in order to detect a noise level during a noise detection operation (see col. 12, line 11 - col. 13, line 13).

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,795,733 teaches a stimulation device that can automatically adapt to different MV electrode configurations when a previously available electrode configuration is no longer available for MV functionality.

U.S. Patent No. 5,824,029 teaches an IMD for performing transthoracic impedance measurements by delivering pulses to a first area and sensing impedance in a second area.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*NRK*

NRK

*2/9/06*

*George Manuel*  
George Manuel  
Primary Examiner